

REMARKS

Claims 1-7 are cancelled without prejudice. Claims 8-29 are newly added. The amendments find support in the claims as originally filed and in the specification. No new matter is added.

Support for newly added claims 8-14 includes page 5, lines 1-27 of the specification. Support for newly added claim 15 includes page 6, lines 1-3, while support for newly added claims 16 and 17 is found on page 6, lines 4-16 of the specification. Support for newly added claim 18 is found on page 3, lines 18-20, page 5, lines 6-8 and lines 14-15, while support for newly added claim 19 is found on page 2 lines 1-13. Support for newly added claim 20 is found on page 3, lines 21-25, while support for newly added claim 21 is found on page 4, lines 1-3. Support for newly added claim 22 is found on page 4, lines 1-3, while support for newly added claim 23 is found on page 9, lines 17-24. Support for newly added claim 24 is found on page 10, lines 1-2, while support for newly added claims 25-28 is found on page 3, lines 4-20. Support for newly added claim 29 is also found on page 3, lines 4-20, with additional support found on page 7, lines 19-22. Support for newly added claims 30-31 is found on page 7, lines 23-27 through page 8, lines 1-2, while support for newly added claims 32 is found on page 4, lines 1-22 and figures 1-2. Finally support for newly added claims 33-34 is found on page 4, lines 4-5.

Drawings

The office action states that new corrected drawings in compliance with 37 C.F.R. 1.121(d) are required in this application. Accordingly Applicant has submitted a new set of drawings.

Claim Objections and Rejections

The Office Action states that claims 5 and 7 are objected to because of minor informalities. The Office Action states that claims 1 and 4 are rejected under U.S.C. 102(b) as being anticipated by Fournier (6,155,990), that claim 6 is rejected under U.S.C. 102(b) as being anticipated by Anderson (6,352,513), and that claims 2 and 3 are unpatentable under 103(a) over Fournier as applied to claims 1 and 4 above, and further in view of Zavada et al.

Applicants have canceled claims 1-7 without prejudice, and have presented new claims which more particularly characterize the invention.

In view of this amendment, the outstanding rejections and objections are rendered moot.

However, Applicants present herein a discussion of how the references cited in the art rejections are distinguished from the newly added claims

Claim rejections 35 U.S.C. . § 102

Fournier does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device comprising a brush with bristles, wherein said bristles are substantially perpendicular from said longitudinal axis, as required by the newly amended claims.

The collecting device used in the methods taught by Fournier comprises a telescoping cylindrical tampon-like cardboard tube which houses a specimen gathering sponge. This sponge is distinct from the brush recited in the instant claims.

Because the method for detecting human papilloma virus taught by Fournier does not encompass the use of a specimen collection device having a brush as required in the instant claims, Applicants contend that Fournier is not an anticipatory reference for the instant newly added claims, all of which encompass the collection device comprising a brush.

Similarly, Anderson does not teach a method for detecting HPV in a vaginal specimen using a specimen collection device having a brush with bristles, that are substantially perpendicular from the longitudinal axis of the brush, as required by the newly added claims.

The collecting device or “personal collector” used in the methods taught by Anderson et al. has an inner sampling assembly positioned within the outer guide. Anderson et al. discloses that the inner assembly guide can include a flexible shaft bearing a collector pad at a first end and a gripping structure at a second end (column 2, lines 27-39).

However, Anderson et al. does not teach a method comprising the use of a specimen collection device having a brush as required in the instant claims. Anderson only uses a collector pad, not a brush. Therefore, Applicants contend that Anderson is not an anticipatory reference for the instant newly added claims, all of which encompass the collection device having a brush.

Claim rejections 35 U.S.C 103

Applicants further contend that Fournier alone, nor when combined with Zavada, does not teach all the limitations of the instant newly added claims. Applicants submit that for a determination of obviousness to be proper, the prior art reference (or references when combined) must teach or suggest *all the claim limitations*. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed above, does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device comprising brush with bristles, wherein said bristles are substantially perpendicular from said longitudinal axis, as required by the newly amended claims.

Zavada et al.'s teaching of methods comprising assaying bodily fluids for the presence of MN proteins using antibodies and proteins does not make up this difference

Therefore, Applicants contend that the teachings of Fournier, either alone or in combination with Zavada, do not teach all the limitations of the newly added instant claims.

In view of these distinctions of the instant invention from both the references cited in the Office Action and the references disclosed in the background section of the instant specification, Applicants contend the instant newly added claims are not anticipated or made obvious by these references.

Conclusion

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Date: April 19, 1996

Respectfully submitted,



Name: Ralph Loren

Registration No.: 29,325

Customer No.: 29933

Edwards Angell Palmer & Dodge LLP

111 Huntington Avenue

Boston, MA 02199-7613

Tel. (617) 239-0100